

5. 510(K) Summary

SEP 13 2012

510(K) SUMMARY: AGFA DX-D FLFS

Common Name: Direct radiography accessory, Full Leg Full Spine application
Classification Name: Image-intensified fluoroscopic x-ray system (21CFR892.1650)
Proprietary Name: DX-D FLFS
Agfa HealthCare N.V.
Septestraat 27
B-2640 Mortsel
Belgium
Contact: Phil Cuscuna, Prepared: July 10, 2012
Telephone: (416) 240-7317
Facsimile: (416) 240-7359

A. LEGALLY MARKETED PREDICATE DEVICES

This is a 510(k) for a new version of Agfa's Full Leg, Full Spine imaging accessory, the DX-D FLFS that is compatible with stationary direct radiography systems. The DX-D FLFS is substantially equivalent to the previous version that is used with computed radiography systems.

B. DEVICE DESCRIPTION

Agfa's DX-D FLFS is a direct radiography accessory, similar to the predicate. The device allows the user to stitch multiple acquired images of long patient anatomies (like a full leg or full spine) into a single patient image. This is particularly useful for making measurements during orthopedic examinations. The DX-D FLFS includes an optional software license for its NX workstation (for image processing) and a patient stand with grid.

Principles of operation and technological characteristics of the new and predicate devices are the same.

C. INTENDED USE

Agfa's DX-D FLFS is indicated for acquiring images for measurements in the orthopedic field (skeleton).

D. SUBSTANTIAL EQUIVALENCE SUMMARY

Agfa's DX-D FLFS has an indications statement that is similar to the predicate, K000159. Their intended uses are the same. The new version works with Agfa's direct radiography systems. The predicate works with its computed radiography systems. Computed radiography and direct radiography systems are both solid-state x-ray imaging devices.

Both the new and predicate device include manual and anatomically-based automatic stitching of images. The DX-D FLFS includes a grid based automatic stitching mode as well.

The devices have the same technological characteristics. Descriptive characteristics are adequate to ensure equivalence.

Differences between the new and predicate devices do not alter the intended diagnostic effect.

| PRODUCT COMPARISON TABLE | | |
|-------------------------------------|---|--|
| | DX-D FLFS (New Device) | Full Leg Full Spine Image Stitching Software (PREDICATE-K000159) |
| Detectors | Agfa DR Detectors | Agfa FLFS CR MD4.1 Cassette and Image Plate. |
| Patient/Detector positioning | DX-D FLFS Stand | CR Full Body Cassette Holder & CR Easylift |
| Detector Sizes | 17x17 in. | 14x17 in. |
| Operator Workstation | Same as predicate | Agfa NX |
| Image stitching | <ul style="list-style-type: none"> • Automatic, grid based • Automatic, anatomy based • Manual | <ul style="list-style-type: none"> • Automatic, anatomy based • Manual |
| Active Matrix | 3056x3056 | 2320x2832 |
| Dynamic Range (acquisition) | 14 bit | 16 bit, sq. root compressed |
| Dynamic Range (display) | Same as predicate | 12 bit |
| Operating system | Same as predicate | Windows 7 |
| Display System | Same as predicate | Standard PC display or separately cleared medical display (e.g. K051901) |

E. TECHNOLOGICAL CHARACTERISTICS

Agfa's DX-D FLFS is an accessory for its direct radiography systems. It includes a non-powered patient stand with grid and image processing algorithms in its NX workstation. The device allows the user to automatically or manually stitch multiple acquired images into a single patient image. Use of the accessory requires an optional Full Leg Full Spine user license.

F. TESTING

Design verification tests confirm the device meets specifications. Stitching algorithms operate as planned with expected measurement accuracy. Performance of the complete system has been validated.

No clinical testing was performed in the development of the DX-D FLFS.

The product, manufacturing and development processes have been shown to conform to safety and management standards including:

PRODUCT STANDARDS

- IEC 60601-1: Medical electrical equipment Part 1: General requirements for basic safety and essential performance. (The patient stand only has been tested according to requirements for mechanical hazards described in Clause 9.)
- DIN EN ISO 10993-5: Biological evaluation of medical devices - Tests for in vitro cytotoxicity

MANAGEMENT STANDARDS

- ISO 14971 Application of Risk Management to Medical Devices
- ISO 13485 Medical Devices - Quality Management Systems - Requirements For Regulatory purposes

G. CONCLUSIONS

This 510(k) has demonstrated Substantial Equivalence as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

SEP 13 2012

Agfa HealthCare N.V.
Mr. David Ledwig
Principal Consultant
Practical Compliance, LLC
P.O. Box 1927
BREVARD NC 28712

Re: K122119
Trade/Device Name: DX-D FLFS
Regulation Number: 21 CFR 892.1680
Regulation Name: Stationary x-ray system
Regulatory Class: II
Product Code: KPR
Dated: July 10, 2012
Received: July 17, 2012

Dear Mr. Ledwig:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

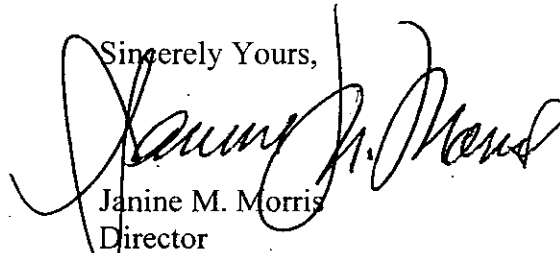
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris
Director

Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K122119

Device Name: DX-D FLFS

Indications for Use:

Agfa's DX-D FLFS is indicated for acquiring images for measurements in the orthopedic field (skeleton).

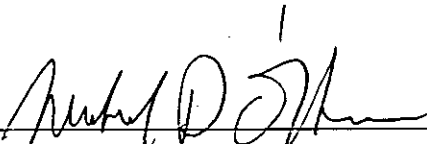
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)


Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K122119

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